

AMENDMENT TO THE CLAIMS

Please amend the claims without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows.

In the Claims:

1. (Previously presented) A topical patch comprising
a therapeutic compound-impermeable backing layer,
a self-adhesive amine-resistant polysiloxane matrix containing at least 1% by weight, of
the therapeutic compound
wherein the polysiloxane matrix is a mixture of a polysiloxane of medium tack
and a polysiloxane of high tack and the therapeutic compound is capsaicin or a
capsaicin analog or mixture thereof, and
a protective film to be removed before use,
in which
 - a. the matrix contains liquid microreservoir droplets comprising an
amphiphilic solvent, in which the therapeutic compound is dissolved, and
 - b. the concentration of the therapeutic compound in the microreservoir
droplets is between 20 and 90% by weight of the saturation concentration
wherein the amphiphilic solvent is a butanediol, 1,3-butanediol,
dipropylene glycol, tetrahydrofurfuryl alcohol, diethylene glycol dimethyl
ether, diethylene glycol monoethyl ether, diethylene glycol monobutyl
ether, propylene glycol, dipropylene glycol, carboxylic acid esters of tri-
and diethylene glycol, polyethoxylated fatty alcohols of 6 - 18 C atoms or
2,2-dimethyl-4-hydroxymethyl-1,3-dioxolane, or mixtures of these
solvents.
2. (Original) The topical patch as claimed in claim 1, in which the therapeutic compound is
capsaicin.
3. (Original) The topical patch as claimed in claim 1, in which the concentration in the
therapeutic compound in the microreservoir droplets is between 40 and 70% by weight of
the saturation concentration.

4. (Previously presented) The topical patch as claimed in claim 1, in which the amphiphilic solvent is 1,3-butanediol, dipropylene glycol, diethylene glycol monoethyl ether, or 2,2-dimethyl-4-hydroxymethyl-1,3-dioxolane, or mixtures of these solvents.
5. (Original) The topical patch of claim 4 wherein the solvent is diethylene glycol monoethyl ether.
6. (Original) The topical patch as claimed in claim 1, in which the microreservoir droplets comprise a viscosity-increasing additive dissolved in the solvent.
7. (Original) The topical patch as claimed in claim 6, in which the viscosity-increasing additive is a cellulose derivative or a high molecular weight polyacrylic acid.
8. (Previously presented) The topical patch of claim 7, in which the viscosity-increasing additive is ethylcellulose or hydropropylcellulose.
9. (Previously presented) The topical patch as claimed in claim 1, in which the proportion of the microreservoir droplets in the matrix is less than 40% by weight, based on the total weight of the matrix .
10. (Previously presented) The topical patch as claimed in claim 1, in which the self-adhesive amine-resistant polysiloxane matrix contains at least 3% of the therapeutic compound the proportion of the microreservoir droplets in the matrix is less than 35% by weight, based on the total weight of the matrix.
11. (Previously presented) The topical patch as claimed in claim 10, in which the self-adhesive amine-resistant polysiloxane matrix contains at least 5% of the therapeutic compound the proportion of the microreservoir droplets in the matrix is between 20 and 30% by weight, based on the total weight of the matrix.

12. (Original) The topical patch as claimed in claim 10, wherein the matrix contains from about 0.5 to about 5% by weight of a silicone oil.
13. (Previously presented) The topical patch as claimed in claim 1, in which the matrix comprises
 - 5 – 10% by weight of capsaicin or a capsaicin analog,
 - 10 – 25% by weight of diethylene glycol monoethyl ether,
 - 0 – 2% by weight of ethylcellulose,
 - 0 – 5% by weight of silicone oil, and
 - 58 – 85% by weight of self-adhesive polysiloxane and the coating weight of the matrix is between 30 and 200 g/m².
14. (Previously presented) The topical patch as claimed in claim 1, in which the matrix consists essentially of
 - 5 – 10% by weight of capsaicin or a capsaicin analog,
 - 10 – 25% by weight of diethylene glycol monoethyl ether,
 - 0 – 2% by weight of ethylcellulose,
 - 0 – 5% by weight of silicone oil, and
 - 58 – 85% by weight of self-adhesive polysiloxane and the coating weight of the matrix is between 50 and 120 g/m².
15. (Previously presented) The patch as claimed in claim 1, in which the backing layer consists of a polyester film 10 – 20 µm thick.
16. (Original) The topical patch as claimed in claim 1, in which the backing layer consists of an ethylene-vinyl acetate copolymer.
17. (Previously presented) A method for the treatment of neuropathic pain which comprises administering the topical patch of claim 1 to a patient in need thereof.

18. (Previously presented) The topical patch as claimed in claim 11, in which the microreservoir droplets comprise a viscosity-increasing additive dissolved in the solvent.
19. (Previously presented) The topical patch as claimed in claim 18, in which the viscosity-increasing additive is ethylcellulose or hydropropylcellulose.
20. (Original) A method for the production of a topical patch as claimed in claim 1, which comprises dissolving the therapeutic compound in an amphiphilic solvent, adding this solution to a solution of a polysiloxane or the matrix constituents and dispersing, coating the resulting dispersion onto a protective layer which is removable again and removing the solvent of the polysiloxane and laminating the backing layer onto the dried matrix layer.